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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,400	06/27/2003	Michael J. Puglia	MSA-3453	7945

7590 06/14/2005

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EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/608,400	<b>Applicant(s)</b> PUGIA ET AL.	
	<b>Examiner</b> Brian J. Sines	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2005.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 27-32 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-16 and 27-32 is/are rejected.  
 7) ☒ Claim(s) 27 is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Objections*

Claim 27 is objected to because of the following informalities: Claim 27 contains a period before “comprising” in the preamble. Appropriate correction is required.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

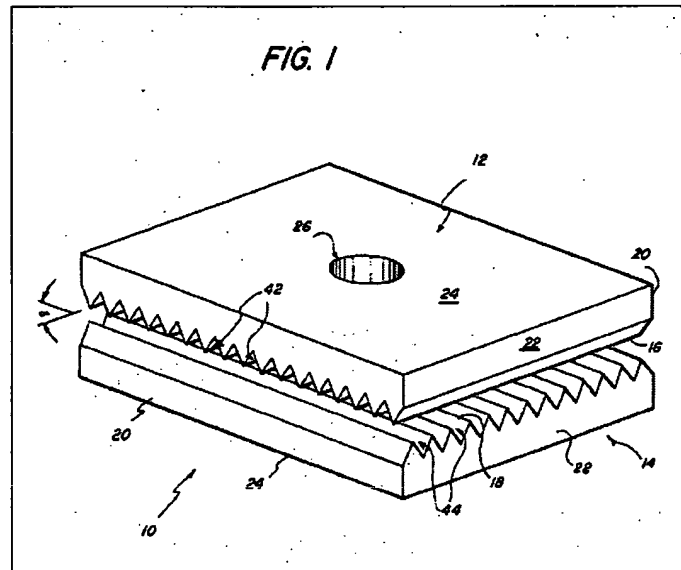
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 1, 5 – 9 and 13 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus (U.S. Pat. No. 4,233,029) in view of Przybylowicz et al. (U.S. Pat. No. 3,992,158).

Regarding claims 1 and 8, Columbus teaches an analytical apparatus (10) comprising: at least one space (e.g., the space between interior surfaces 16 & 18) for containing a test sample and a reagent on a substrate (e.g., the bottom surface 18); a microstructure (grooves 42 & 44) disposed in the space for directing the test sample over the substrate in a uniform manner. As

fluid is introduced into the space via port 26, the introduced fluid would displace and thereby purge any air contained within this space during use (see col. 3, line 16 – col. 4, line 68; figure 1).



Columbus is silent to specifically teaching that a reagent or conditioning reagent is immobilized on a substrate surface. Although Columbus does teach that it can be desirable to include a reagent disposed on at least a portion of one or both substrate surfaces as disclosed by Przybylowicz et al. (see col. 9, lines 50 – 68). Przybylowicz et al. do teach the immobilization of reagents on a substrate layer contained within an analytical microfluidic apparatus (see col. 8, lines 44 – 66). Hence, as evidenced by Przybylowicz et al., a person of ordinary skill in the art would have recognized the suitability of incorporating the use of immobilized reagents within an analytical apparatus for the intended purpose of facilitating effective sample analysis (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of immobilized reagents, as taught by Przybylowicz et al., with the analytical apparatus disclosed by Columbus. The Courts have held

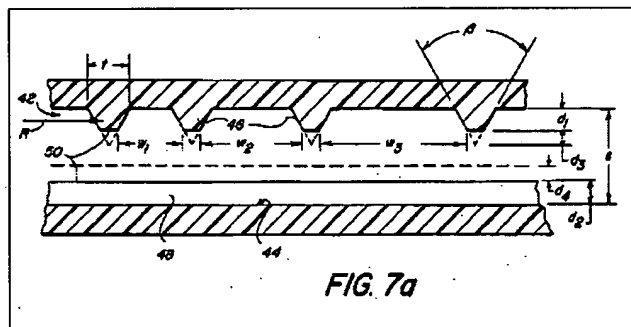
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that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate immobilized reagents onto the substrate surface of the Columbus apparatus in order to facilitate effective sample analysis.

Regarding claim 5, Columbus teaches that the microstructure (e.g., groove 42) is also positioned above the substrate (e.g., substrate surface 18) (see figure 1).

Regarding claim 6, Columbus teaches that the microstructure (e.g., groove 44) can also be in contact and further integrated within the substrate (e.g., substrate surface 18) (see figure 1).

Regarding claim 7, Columbus also teaches the incorporation of a microstructure (truncated ridges 46) comprising a ramp or slanted or inclined portion and a substrate plateau (e.g., the flat top surface of the truncated ridge 46) (see col. 8, lines 1 – 67; figure 7a).



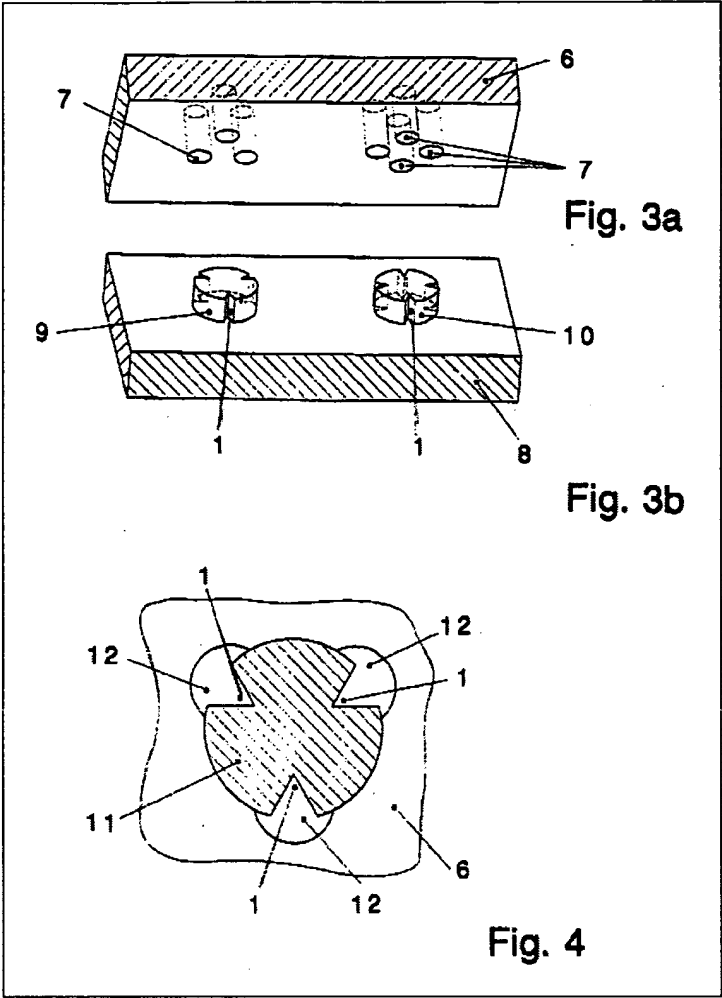
Regarding claims 9 and 13 – 16, as discussed above, Columbus in view of Przybylowicz et al. teaches all of the apparatus structure recited in the claimed method, which merely recites the conventional operation of that apparatus structure. Regarding claim 9, the recited well structure is essentially equivalent to the space (e.g., the space between interior surfaces 16 & 18) for containing a test sample and a reagent on a substrate (e.g., the bottom surface 18) contained

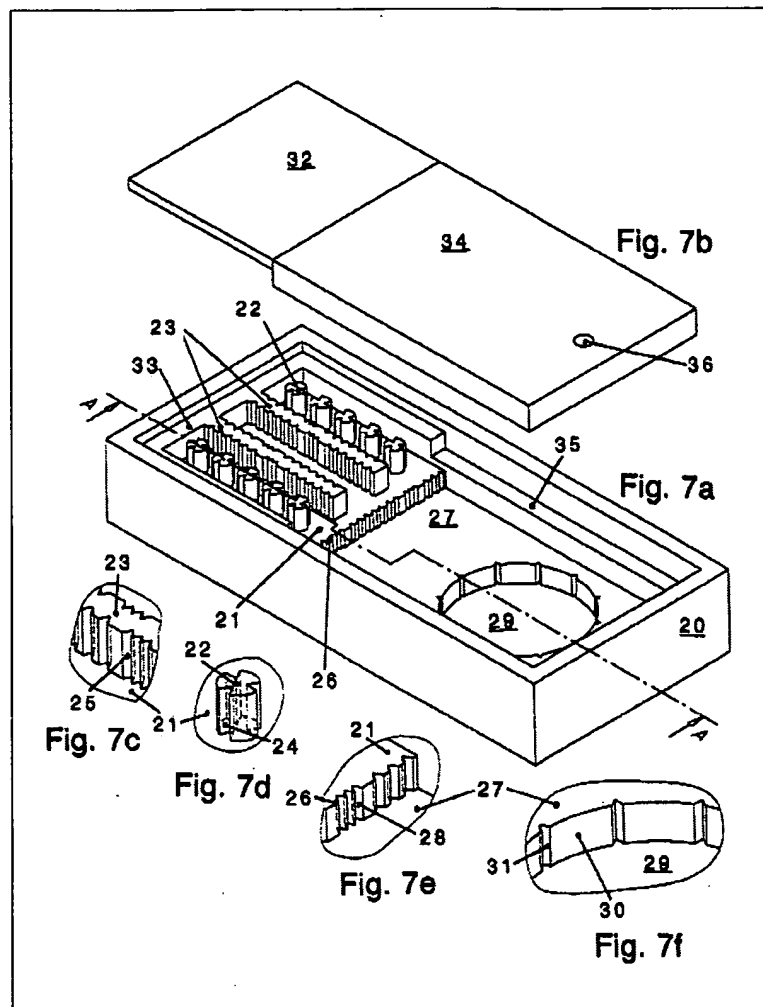
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within the apparatus of Columbus , as discussed above. Therefore, it would have been obvious to a person of ordinary skill in the art to perform the methodology recited in the instant claims upon the apparatus of Columbus, as such is the intended operation of that apparatus.

2. Claims 2 – 4, 10 – 12 and 27 – 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus in view of Przybylowicz et al., as applied to claims 1, 5 – 9 and 13 – 16 above, and further in view of Peters (U.S. Pat. No. 6,296,126 B1).

Regarding claim 2, neither Columbus nor Przybylowicz et al. teach the incorporation of microstructures comprising post or column structures disposed at a right angle to the flow of the test sample. Peters does teach the use of post or column structures (9, 10 & 22) within an analytical microfluidic apparatus for facilitating effective fluid flow within the apparatus (see col. 3, line 30 – col. 39; figures 3b & 7a).





Hence, as evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of these post or column structures within an analytical microfluidic apparatus for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these post structures within a microfluidic apparatus for facilitating effective fluid control. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ



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375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of an array of post structures comprising one or more than one column of posts disposed at a right angle to the flow of fluid within the microfluidic apparatus of Columbus.

Regarding claim 3, as illustrated in figure 7a, Peters indicate that multiple columns of posts (22 & 23) may be incorporated into the apparatus. In addition, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a second column of posts, as indicated by Peters, within the Columbus apparatus in order to facilitate effective fluid flow control.

Regarding claim 4, Peters does teach the incorporation of wedge-shaped cut-out structures (columnar projection 9 having wedge-shaped cut-outs 1) within a microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4). Consequently, a person of ordinary skill in the art would have recognized the suitability of incorporating such wedge-shaped cut-out post structures within an analytical microfluidic device for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate post structures comprising at least one wedge-shaped cut-out as recited in claim 4, to provide for effective fluid flow control.

Regarding claims 10 – 12 and 27 – 32, as discussed above, Columbus in view of Przybylowicz et al. and Peters teaches all of the apparatus structure recited provided for in the

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claimed method, which merely recites the conventional operation of that apparatus structure.

Therefore, it would have been obvious to a person of ordinary skill in the art to perform the methodology recited in the instant claims upon the apparatus taught by Columbus in view of Przybylowicz et al. and Peters, as such is the intended operation of that apparatus.

### ***Response to Arguments***

1. Regarding the rejection of claims 1, 5 – 9 and 13 – 16 under 35 U.S.C. 103(a) as being unpatentable over Columbus in view of Przybylowicz et al., applicant's arguments filed 3/31/2005 have been fully considered, but they are not persuasive. This rejection is maintained. As discussed above, Columbus teaches an apparatus, which comprises certain microstructures (e.g., grooves 42 & 44), which permits the controlled transport of a fluid sample in a uniformly spreading manner within the apparatus. Columbus does teach that it can be desirable to include a reagent disposed on at least a portion of one or both substrate surfaces as disclosed by Przybylowicz et al. (see col. 9, lines 50 – 68). Przybylowicz et al. merely teach an example of the immobilization of reagents on a substrate layer contained within an analytical microfluidic apparatus (see col. 8, lines 44 – 66). The applicant indicates that the pending claims, in particular claims 1 and 9, are being interpreted too broadly when compared to the cited prior art. However, the applicant is improperly reading limitations from the specification into the claims when comparing the claims to the prior art apparatus. The applicant is advised that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993); *In re Barr*, 170 USPQ 330 (CCPA 1971). “The PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be

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understood by one of ordinary skill in the art.” See *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). “During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.” See *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). “The PTO broadly interprets claims during examination of a patent application since the applicant may ‘amend his claim to obtain protection commensurate with his actual contribution to the art.’”(quoting *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550 (CCPA 1969)). See *In re Yamamoto*, 740 F.2d 1569, 1571, 222 USPQ 934, 936 (Fed. Cir. 1984). The applicant cannot read limitations set forth in the description into the claims for the purpose of avoiding the art. See *In re Sporck*, 155 USPQ 687 (CCPA 1967). As discussed above, the prior art teaches all of the positively recited structure of the claimed apparatus. Although the apparatus as taught by the prior art may not be what the applicant intends as their claimed invention, the claims still encompass the teachings of the prior art. The claims still do not exclude the teachings of the prior art. In conclusion, the applicant is further advised that the Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

2. Regarding the rejection of claims 2 – 4 and 10 – 12 under 35 U.S.C. 103(a) as being unpatentable over Columbus in view of Przybylowicz et al., as applied to claims 1, 5 – 9 and 13

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– 16 above, and further in view of Peters, applicant's arguments filed 3/31/2005 have been fully considered, but they are not persuasive. This rejection is maintained. The applicant argues that although Peters does show an apparatus having wedge-shaped cut-outs, Peters does not suggest the use which the instant claims disclose. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to applicant's argument that Peters does not indicate the use of wedge-shaped cut-outs with an apparatus as disclosed by Columbus in view of Przybylowicz et al., the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Peters does teach the incorporation of wedge-shaped cut-out structures (columnar projection 9 having wedge-shaped cut-outs 1) within a microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4). The Courts have held that the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from the knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). For sources of rationale supporting an obviousness rejection under 35 U.S.C.

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103, the rationale may be in a reference, or reasoned from common knowledge in the art, scientific principles, art-recognized equivalents or legal precedent (see MPEP § 2144). Hence, as evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of these post or column structures within an analytical microfluidic apparatus for the intended purpose of further facilitating effective fluid control (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these post structures within a microfluidic apparatus for facilitating effective fluid control. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of an array of post structures within a microfluidic apparatus to provide for the structure as recited in the instant claims.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

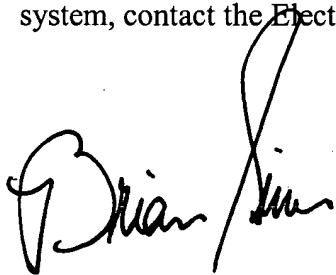
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Brian J. Sines". The signature is stylized with a large, looping initial "B" and a long, sweeping underline that extends to the right.